84-1752

Office-Supreme Court, U.S.
FILED
MAY 6 1985
ALEXANDER L. STEVAS
CLERK

No.

IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1984

LORRIN LEE SIXTA,

Petitioner

vs.

UNITED STATES OF AMERICA,

Respondent.

ON WRIT OF CERTIORARI TO THE
10TH CIRCUIT COURT OF APPEALS

ELWYN L. CADY, JR.
1919 Drumm Avenue
Independence, Mo.
64055
816-252-2219

KENNETH I. GRISSINGER
911 Argyle Building
306 East 12th Street
Kansas City, Mo. 64106

Attorneys for Petitioner

93

QUESTIONS PRESENTED FOR REVIEW

1. Whether the court wrongfully directed invasion of work product trial preparation materials.

2. Whether the trier of fact erred in considering matters Dehors the record.

3. Whether the court erred in failing to employ the substantial factor test in interpreting Minnesota law of proximate causation.

4. Whether the trier of fact had prejudged the merits of the case in advance of reception of the total evidence and arguments of counsel.

TABLE OF CONTENTS

Questions Presented for Review i

Opinions Below 1

Jurisdiction 1

Statute Involved 2

Statement of Case 2

Argument 8

1. The court wrongfully directed invasion of workproduct trial preparation materials 8

2. The trier of fact erred in considering matters dehors the record 13

3. The court erred in failing to employ the substantial factor test in interpreting Minnesota law of proximate causation 16

4. The trier of fact had prejudged the merits of this case before reception of the total evidence and arguments of counsel 20

Conclusion 22

Appendix

Bench Ruling, Trial Court A1

Order and Judgment, Court of Appeals. A32

Petition for Rehearing Denial A42

Public Law 94-380 ("Swine Flu"). A44

TABLE OF AUTHORITIES

Agar v. Jane C. Stormont Hospital and Training, 622 F.2d 496,500 . . . . A35

Alvarez vs. United States, 495 F. Supp. 1188 . . . . . 8,A4 A17

Belcher vs. Bassett Furniture Company Industries, Inc., 588 F. 2d 104-12 A36

Bernloehr vs. Central Livestock Order Buying Company, 296, Minn. 222, 208 N.W. 2d 753. . . . . A19,A40

Bishop v. St. Paul City Ry, 48 Minn. 26, 50 N.W. 927, cited at 25 Harv. L. Rev. 107. 19

Dellwo v. Pearson, 259 Minn. 452, 107 N.W. 2d 859, 97 ALR 2d 866. 19

Deward v. Clough, 245 Cal. App. 2d
439, 54 Cal. Rptr. 68, 72. 21

Grundy v. United States, 728
F. 2d 484, 489. . . . . .A41

Hickman v. Taylor, 329 U.S. 495. . . . 8,9,11

Jensen v. Dikel, 244 Minn. 71, 69
N.W. 2d 108. 13

Morris v. Nowotny, 68 Wash. 2d
679, 415 P. 2d 4,6 22

Richards v. United States,
369 U.S. 1 . . . . . .A18,A34

Ryan v. Hatfield, 578 F. 2d 275,
276 . . . . . 11,A35

Silkwood v. Kerr-McGee Corp., 563
F. 2d 11, 433, 436. . . . . A35

Silver v. Redleaf, 194 N.W. 2d
271, 273 . . . . . A40

United States v. Bump,
605 F. 2d, 548, 551 . . . . . 8,A37

United States v. Nobles,
422 U.S. 225, 238n11 8

Upjohn Company v. United States,
449 U.S. 383 9,11

Walstad v. University of Minnesota
Hospitals, 422 F. 2d 634 . . . . . .A18,A40

Walton v. Jones, 286 N.W. 2d
710. . . . . A18,A40

Watson v. Rheinderknecht,
82 Minn. 235, 84 N.W. 798,
799-800 16

Other Authorities

American Law Reports, annotations

95 ALR 2d at 355 13

35 ALR 3d 412 3

Rules

F.R. Civ. P. 26 (b) (3) A34,A37

F.P. App. D. 34(a) A32

F.P. App. D. 35 . . . . . .A43

10th Cir. R. 10(e) A32

10th Cir. R. 17(b) A41

Federal Rule of Evidence 803 (18) 13

Legal Text and Law Reviews

GREEN, RATIONALE OF PROXIMATE CAUSE
(Vernon, 1927) 17

James and Perry, "Legal Cause",
60 Yale L.J. 761 19

Malone, "Ruminations on Cause-In-Fact," 9 Stanford L. Rev. 60 19

Morris, "Proximate Cause in Minnesota," 34 Minn. L. Rev. 185 19

Patterson, "Cause in Law and Metaphysics", 10 Can. Bar Rev. 645 . . . 19

Prosser, "The Minnesota Court on Proximate Cause," 21 Minn. L. Rev. 19 . .19

Smith, H.W., "Components of Proof in Legal Proceedings," 51 Yale L.J. 537 . 13-14

Smith, J., 25 Harv. L. Rev. 103, 223, 303, 309-310. 18

4 WEINSTEIN'S EVIDENCE 803-252 et seq. . . . 4

5 WIGMORE, EVIDENCE (Chadbourn rev.) 32 . . 10

Other Literature

Annals of Neurology, Vol.9 supplement, p.65 10

Bridgman, THE LOGIC OF MODERN PHYSICS 91 19

Bunge, CAUSALITY: THE PLACE OF THE CAUSAL PRINCIPLE IN MODERN SCIENCE . . . 20

Churchman, THEORY OF EXPERIMENTAL INFERENCE 198, 199 20

Cohen and Nagel, AN INTRODUCTION TO
LOGIC AND SCIENTIFIC METHOD
method 246 et seq. 20

Dewey, LOGIC: THE MEMORY OF INQUIRY
442 et seq. 20

Dyck, PERIPHERAL NEUROPATHY, Ch. 56 . . . .A25

Frank, MODERN SCIENCE AND ITS
PHILOSOPHY 53 et seq 20

Jeans, PHYSICS AND PHILOSOPHY
98, 102-3, 145, 173, 190, 194. 20

Kennedy, Danielson, Mulder and
Kurland, "Guillain-Barre Syndrome:
42-Year Epidemiologic Clinical Study,"
53 Mayo Clinic Proc. 93 . . . . . .5,15,A25

Morgenbesser, Review of Bunge,
supra, Scientific American
Feb. 1961, p. 175 20

Pearson, THE GRAMMAR OF SCIENCE c.4,
Secs. 1,8; c. 5 19

Reichenbach, ATOM AND COSMOS
268 et seq. 20

Saida, "Allergic Neuritis Induced by Galactocerebroside," Supp. 9, Annals of Neurology, April 1981 . . . . A16

Schonberger, "Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program of 1976," Am. J. Epidemiology 15,A24

von Mises, POSITIVISM 152 et seq. 20

Statute

42 U.C.S. Sec. 247b 2,A33

28 U.S.C. 1346(b) 2674 . . . . . A44

IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1984

LORRIN LEE SIXTA

Petitioner,

vs.

UNITED STATES OF AMERICA

Respondent.

ON WRIT OF CERTIORARI TO THE
10TH CIRCUIT COURT OF APPEALS

OPINIONS BELOW

No opinions of the Court of Appeals (App. A3) is not yet reported. No report of the trial judge's disposition (App. A1) appears.

JURISDICTION

The judgment of the Court of Appeals was entered on December 7, 1984. Timely Motion for Rehearing was filed, and was

denied on February 7, 1985. This court has jurisdiction under U.S.C. Sec. 1257 (3).

STATUTE INVOLVED

National Swine Flu Immunization Program of 1976, 90 Stat. 1113, 42 U.S.C. Sec. 247b, etc. (App. A 44).

STATEMENT OF THE CASE

This is one of over 1,300 cases conducted as Multi-District Litigation under the caption, In re Swine Flu Products Liability Litigation, 446 F. Supp. 244 (D.D.C.). Sixta's particular complaint sought $6,000 for past medical expenses, $150,000 for future medical expenses, $1,700,000 for loss of earning capacity, $5,000,000 as general damages for pain, mental anguish, fear and related matters of permanent injury and loss of enjoyment of life. (Though the case was bifurcated and the issue of damages is slated for the second trial, there was testimony adduced by the government through its witness that Sixta sustained permanent damage.)

1. Invasion of Work Product

Waiving ordinary procedure under the new federal rules of evidence limiting expert testimony discovery to interrogatories, Sixta's counsel produced Dr. Morgan for deposition December 3, 1980. Said counsel made timely objection to invasion of work product. Briefly, Sixta's position was summarized in his Memorandum in Support of Motion to Certify (later denied, so that the direct order for production was by the trial court):

> In advance of each deposition, plaintiff has, and will continue, to furnish a 'CV' for each ---- designating educational background, contributions to the literature, memberships, etc.
>
> What plaintiff will not do, unless directed by the Court of Appeals otherwise, is to permit invasion of 'work product' --- now designated "trial preparation materials" --- under federal authority. See annotation, 35 ALR 3d 412.
>
> ROLE OF MORGAN AS CONSULTANT AND EXPERT WITNESS
>
> As examination of the materials supplied by the government in its various motions will reveal, Morgan

was employed by plaintiff's counsel both as consultant and as an expert witness. Inasmuch as Cady was almost 30 years from his formal medical coursework he required an 'update' from the leading immunologist in Kansas, with basic education in Minnesota --- Morgan. Cady and Morgan had taught forensic immunology together back about 1953 at the University of Kansas School of Medicine and they are both Fellows of the American Academy of Forensic Sciences, now headquartered in Colorado Springs.

Cady and Morgan proceeded jointly, with Morgan as agent of counsel, to medical and scientific libraries and other sources, particularly the University of Kansas Medical School Library where they conducted a thorough review of the immunological literature, particularly directed to the various matters in the instant litigation wherein literature might play a role. As is noted with respect to Federal Rules of Evidence 803 (18), see WEINSTEIN'S EVIDENCE, Vol. 4, 803-252 et seq., previous basic use of literature was for the purpose of cross examining opinion witnesses. The new rule permits incorporation of literature on direct apparently as original evidence under certain circumstances. It should be emphasized that plaintiff's counsel are not seeking the incorporation of textual statements as direct evidence --- they are producing three experts who are highly qualified and prepared to state their enlightened opinions independently --- not tying

> themselves to any presumed 'authority'.
>
> Plaintiff's counsel, however, it is submitted, are properly within their rights to employ an expert as a consultant to 'educate them' on the literature so that proper cross-examination can be adduced at trial. AND THE GOVERNMENT IS NOT ENTITLED TO DISCOVERY OF THIS WORKPRODUCT undertaken with the aid and agency of employed experts.

Sixta's brief on appeal set forth what happened after the trial court denied his MOTION TO CERTIFY:

> Sixta produced Dr. Morgan for a reconvened deposition, not placing the witness in a position of possible contempt charges by refusing to permit discovery, but vehemently reasserting his objection to the disclosure of workproduct trial preparation materials (Vol. 13). Particularly significant were a three-page write-up (Vol. 13, p. 9), a notebook (Vol. 13, p. 10), and file cards (Vol. 13, pp. 10-12) --- in effect the "playbook" of forensic immunology approach to this case.

2. Material Dehors the Record

The trial judge in his bench ruling specifically relied on an article, Kennedy, et al, "Guillain-Barre Syndrome: A 42- Year Epidemiologic and Clinical Study, "53 Mayo

Dr. Nathanson testified for the government in response to hypothetical questioning, not on a review of his medical records. Less than three hours later the trial judge held that he had testified as to his opinion "based on his review of Plaintiff's medical records and his background" (App. A20). The Suggestion in Support of Sixta's Motion to Alter Judgment included:

> It was evident that the Court prepared its order prior to the argument of counsel. Many hours were spent in summarizing the case to help guide the Court through the testimony --- all to no avail --- which in essence denied plaintiff right to a fair trial. All litigants are entitled to absolute presumption of open mindedness until all arguments are completed. Any less is a contravention of a fair trial.

The last witness at trial, Dr. Nathanson, appearing for the government appeared at 9:30 P.M., April 22nd. A recess was taken at 8:10 A.M. (Vol. 17, p. 292) and at 8:45 A.M. closing arguments began (Vol. 17, p. 293). During the recess,

Russell Welch, defense trial counsel of record in Alvarez, 495 F. Supp. 1188, and who had taken deposition testimony in the instant case, was invited into chambers ex parte by the trial court. At the conclusion of oral arguments at 9:45 A.M., a recess of 15 minutes was taken, whereupon the trial court proceeded to "deliver its bench ruling".

ARGUMENT

1. THE COURT WRONGFULLY DIRECTED INVASION OF WORKPRODUCT TRIAL PREPARATION MATERIALS

The Court of Appeals, rejecting Sixta's request for oral argument, has obviously failed to grasp the thrust of his brief before: Bump is cited (App. A37) which is confined to the attorney-client privilege and this court has consistently followed the rule that the Hickman protection for work product is distinct from and much broader than the attorney-client privilege. See U.S. vs. Nobles, 422 U.S. 225, 238n11,

Upjohn, 449 U.S. 383, 400.

Sixta's brief proceeded:

F.R. Civ. P. 26 (b) (3) provides that "Subject to the provisions of subdivision (b) (4) of this rule (inapplicable herein since Morgan fully testified on his opinion and the basis thereof without objection), a party may obtain discovery of documents and tangible things otherwise discoverable * * * and prepared in anticipation of litigation or for trial by or for another party or for that other party's representative (including his attorney, consultant * * * or agent) only upon a showing that the party seeking discovery has substantial need of the materials in the preparation of his case and that he is unable without undue hardship to obtain the substantial equivalent of the materials by other means. In ordering discovery of such materials when the required showing has been made, the court shall protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning the litigation."

Just as in the leading Hickman v. Taylor, 329 U.S. 495, the record herein is devoid of any showing by the government under this rule. The strong public policy for non-disclosure was most recently underlined in Upjohn Company v. United States, 449 U.S. 383.

Prejudice is demonstrated by the fact that the government disgorged citations of immunology literature review, a "playbook type" notebook and a 3-page "gameplan".

The government thereupon in presentation of its expert testimony carefully omitted any testimony by an immunologist. Indeed, the one witness with credentials in immunology, specifically --- after presumed overnight consultation with government counsel --- made it clear that he was not testifying as an immunologist and in agreeing that an immunologist was more qualified on the causation issue, reiterated that his remarks were confined to epidemiology. Consequently, the government effectively shielded its evidence from cross-examination -- "beyond any doubt the greatest legal engine ever invented for the discovery of truth. 5 WIGMORE, EVIDENCE (Chadbourn rev.) 32. Indeed, by deliberately leaving Arnason "at home", and bringing only portions of his deposition, Arnason -- who had been a "marching witness" for the government in previous litigation was also shielded from cross-examination especially on his change of viewpoint as shown by his recent writings with respect to the validity of a prolonged interval between Swine flu vaccination and GBS occurring in particular situations; the distinction between "precise cause" as discussed in his article in the Vol. 9 supplement, Annals of Neurology, p. 65, and "etiology" in the courtroom; validity of the equivalence,

immunologically, of EAN and GBS; and of relapsing features in patients. It is submitted that cross-examination would virtually destroy the entire predicate of the court's analysis of Arnason's expertise!

Inasmuch as the government's witness Ziegler agreed that immunology has progressed greatly in the last three years, it is reasonably to be expected that at the time of retrial herein, assuming reversal and a holding that Sixta's position is sound, confidentality of the updated "playbook" would be properly secured under the Rule. Analogous would be the updating in professional football "playbooks" as players are traded from team to team. Consequently, even though the materials at this original trial were not protected, Sixta would be singly benefitted upon the retrial by this Court's remedial action.

The Court of Appeals requires plaintiff o carry a burden of proof on trial reparation materials indicating that the atter is discretionary. This is contrary to he strong holdings of Hickman (329 U.S. 495 t page 512) and Upjohn. The court's itation to Ryan and Silkwood (App. A35) issed the issue. Ryan dealt with relevancy ith respect to the scope of discovery which

provides for discretion "unless otherwise limited by order of the Court in accordance with these rules." Silkwood deals with discretion in permitting consideration of a motion out of time. It does not bear on the mandatory provision of Rule 26.

Further, the very citation the Court of Appeals of Belcher (App A36) actually emphasizes the strict standard of a special showing of substantial need which is the government's preliminary burden. (Belcher, 588 F.2d at 908). Here there was no such showing at all so that there was no room for the application of discretion. The Court of Appeals apparently presumed there had been a hearing on this that somehow was not made part of the record. Actually, there was no hearing held!

Further illustrative of the Court's confusion is its assertion that the government's strategic approach could be based on knowledge that "plaintiff was planning to call an immunologist to

testify." It would be supposed ordinarily that such circumstance would move the government to call its immunologist witnesses, rather than shield them from cross-examination. It is when government counsel realized the ammunition Sixta's counsel had for his cross-examination that the government might well be inclined to "leave Arnason at home".

2. THE TRIER OF FACT ERRED IN CONSIDERING MATTERS DEHORS THE RECORD

Again the Court of Appeals, having denied oral argument, just refused to consider Sixta's point 2. The argument proceeded:

> It is a fundamental rule that jurors may not receive evidence out of court (95 ALR 2d at 355) and the proscription logically applies to the judge when he is the trier of fact. The trier is to consider the evidence before him - - - not move dehors the record to manipulate technical mechanisms (Jensen v. Dikel, 244 Minn. 71, 69 N.W. 2d 108) or technical literature. Granted that judges may have imponderable preconceptions based upon their general experience (Smith, "Components of Proof in

Legal Proceedings," 51 Yale L. J.537), when the judge sits as a trier of fact he goes beyond permissible bounds, when, as here, he digs out a particular article, albeit from the Mayo Clinic, and employs it in bolstering his "bench judgment" (Vol. 17, p. 328).

Giant strides outside the record are taken when a judge presumes to "review the medical literature" (Vol. 17, p. 327).

The court's ex cathedra expression that when the exact organic cause of GBS has not been scientifically proven that proximate cause can only be established by resort to clinical observations and epidemiologic studies (Vol. 17, p. 327) has absolutely no support in the evidence introduced herein.

Indeed, it was admitted by epidemiologic literature presented that the technique involved "counting noses" of those being diagnosed as GBS cases under a voluntary surveillance program which ended January 31, 1977 ---long before Sixta was diagnosed. Sixta's case was never counted in any epidemiologic study presented! Justice hinges on what happened in Sixta's situation --- not on garbled statistics drawn by the government through a ploy of calling up busy physicians around the country and soliciting criteria "floated" by the government itself in anticipation of litigation.

The lower court suggests a misreading of the record with respect to the Kennedy article (App A38) implying that because Schoenberger cites Kennedy the trial court can then rely on Kennedy in making up its mind on the issues of the case at hand. The Kennedy article is carried as footnote 12 in the Schoenberger article. The only statements involving that citation carried in Schoenberger (as Defense Exhibit Q) are these:

> The previously reported average annual incidence rates ranged between 6 and 16 cases per million people per month (7-12). The 40 cases in the largest of these populations based studies showed, by date of onset, and even distribution throughout all seasons (12).
>
> * * * Another type of evidence for the etiologic relationship of influenza vaccination and GBS included the marked lower proportion of vaccinated compared to unvaccinated cases with a history of a recent acute illness within four weeks before onset, 32.8 per cent versus 61.8 percent, respectively. This evidence derives its strength chiefly from the only two studies in the literature comparing incidence of a disorder among patients with GBS with the

incidence among a control group (12, 13).

Now the trial judge takes the Kennedy citation, no opportunity to cross-examine Kennedy being afforded, and weaves it into a rationale for denying Sixta relief.

3. THE COURT ERRED IN FAILING TO EMPLOY THE SUBSTANTIAL FACTOR TEST IN INTERPRETING MINNESOTA LAW OF PROXIMATE CAUSATION.

The complete misapprehension by the Court of Appeals on the Minnesota Law of Proximate Cause (App. A40) is apparent from the text of Sixta's brief:

A. A Single Simple Determination

> Since the sole point at issue on the first trial was that of causation, primary emphasis here is directed to proximate cause. It should be realized, moreover, that Minnesota jurisprudence of proximate cause required consideration of the wrongful act and, secondarily only, the results: "It is the general character of the act, and not the general result, that the law primarily regards in this connection." Watson v. Rheinderknecht, 82 Minn. 235, 84 N.W. 798, 799-800, per Judge Collins. Consequently, the nature of the "gunning" of the vaccine and the circumstances thereof should be given primary evaluation in determining causal liability.

Minnesota causation law was a primary source in the formulation of the famous Smith substantial factor test. Fortunately, we have the masterful monograph of Leon Green as a guide (along with Prosser's analysis of Minnesota cases when he was a Minnesota Professor).

Though Green's book, GREEN, RATIONALE OF PROXIMATE CAUSE, (Vernon, 1927), is out in a 1976 Rothman Reprint, it may not be immediately at hand. We therefore line out the following incisive quotations considered helpful here:

> " * * * A point of equal importance to be observed is that in any given case the inquiry is not directed toward discovering the cause of the damage, but is whether the defendant's conduct was a cause of the damage (134).
>
> * * * The court is not set up as a scientific commission to ferret out all of these factors and apportion the respective shares of the loss to each. The court is only interested in determining what part the conduct of defendant played in producing the result. Nor is it quite this. The court wants to know whether the defendant's conduct played such part as to make him responsible. The complainant himself has by allegations limited the inquiry to the conduct of the person charged. The consideration of the other cause factors is incidental and only material on two points, First, whether the part played by any other cause factor is a hazard for which defendant should

be held and second, whether in the light of all the other factors, the defendant's conduct played an appreciable part in the result. . .

"* * * Perhaps the very simplicity of the inquiry has caused it to be looked upon with misgivings. The tendency of lawyers or any other group of experts is total involvement. They instinctively feel that appropriate raiment is needed in which to garb an idea. Lawyers employ terminology of their science lavishly. Frequently the idea is lost in its dress. This has happened in dealing with this simplest of inquiries. 'Cause', although irreducible in its concept, could not escape the ruffles and decorations so generously bestowed: remote, proximate, direct, immediate, adequate, efficient, operative, inducing, moving, active, real, effective, decisive, supervening, probable and others. The difficulty now is in getting anyone to believe that so simple a creature could have been so extravagantly garbed. . ."

B. Minnesota Law Of Legal Cause Is Quite Liberal, Especially When Compared To That Of Colorado (As Noted In Alvarez).

Jeremiah Smith's formulation of the substantial factor test (25 Harv. L.Rev. 103, 223,303, 309-310), to-wit: "Was defendant's conduct a substantial factor in producing

plaintiff's injuries.?", approved by Green (op cit. at 139, Green also using the term "appreciable factor" --- which has judicial sanction), found reliance on a leading Minnesota case in which paralysis ensued after many months of latency between trauma and clinical symptoms. Bishop v. St. Paul City Ry, 48 Minn. 26, 50 N.W. 927, cited at 25 Harv. L. Rev. 107.

Judge Loevinger, in Dellwo v. Pearson, 259 Minn. 452, 107 N.W. 2d 859, 97 ALR 2d 866, indicated the liberality of Minnesota doctrine in determining legal cause, significantly citing literature:

Prosser, "The Minnesota Court on Proximate Cause," 21 Minn. L. Rev. 19

Morris, "Proximate Cause In Minnesota," 34 Minn. L. Rev. 185

Malone, "Ruminations On Cause-in-Fact," 9 Stanford L. Rev. 60

James and Perry, "Legal Cause," 60 Yale L.J. 761

Patterson, "Cause in Law and Metaphysics" 10 Can. Bar Rev. 645

Pearson, THE GRAMMAR OF SCIENCE c.4, Secs. 1,8; c.5

Bridgman, THE LOGIC OF MODERN PHYSICS 91

Reichenbach, ATOM AND COSMOS 268 et seq.

Cohen and Nagel — AN INTRODUCTION TO LOGIC AND SCIENTIFIC METHOD 246 et seq.

Dewey, LOGIC: THE MEMORY OF INQUIRY 442 et seq.

Jeans, PHYSICS AND PHILOSOPHY 98, 102-3, 145, 173, 190 194

Churchman, THEORY OF EXPERIMENTAL INFERENCE, 198, 199

Frank, MODERN SCIENCE AND ITS PHILOSOPHY 53 et seq.

von Mises, POSITIVISM 152 et seq.

Bunge, CAUSALITY: THE PLACE OF THE CAUSAL PRINCIPLE IN MODERN SCIENCE

Morgenbesser, Review of Bunge, supra, Scientific American, Feb. 1961, p. 175

4. THE TRIER OF FACT HAD PREJUDGED THE MERITS OF THIS CASE BEFORE RECEPTION OF THE TOTAL EVIDENCE AND ARGUMENTS OF COUNSEL

The Court of Appeals conclusion that there is no evidence of predetermination

flies in the face of evidentuary facts from which the logical inference is drawn that there was prejudgment. Again, the court failed to come to grips with Sixta's textual arguments:

> The inference is clear that the trial judge had his findings of fact and conclusions of law composed before the testimony of Nathanson on the morning of April 22nd and the final arguments of counsel. The time intervals and the conference ex parte with Welch add up to the reasonable conclusion that the court's mind was made up prior to final submission of the case. Deliberate determination that Nathanson had reviewed Sixta's medical records contrasting with the obvious fact that his testimony was adduced only upon hypothetical questioning such testimony being given only minutes before the judge gave his "bench judgment", clinches the reasonableness of the inference.
>
> In light of case law, it is also significant that the judge did not refute the allegation contained in Suggestions In Support of Motion To Alter Judgment Or For New Trial.
>
> The situation here bears striking resemblance to that obtaining in Deward v. Clough, 245 Cal. App. 2d 439, 54 Cal. Rptr. 68, 72. In that case all the evidence was in and only the opening argument was concluded. As Presiding Judge Pierce held: "(J)uror Simard had

prejudged the case. This was misconduct and it was serious.

> "Cynics, critical of the jury system, have observed that prejudgment is an inevitable concomitant of the system since juries are composed of human beings and --- more particularly --- of laymen unschooled in withholding decision; unaware that such restraint is a vital part of meting out impartial judgment * * *."

"(I)t is a generally accepted principle of law that a party to a lawsuit is entitled to have disputed questions of fact decided by a dispassionate trier of facts." Morris v. Nowotny, 68 Wash. 2d 679, 415 P. 2d 4,6.

CONCLUSION

The Swine Flu emergency legislation promises "equitabie handling of any claim" (App A50). Consequently, the writ should be granted.

Respectfully submitted,

ELWYN L. CADY, JR.
1919 Drumm Avenue
Independence, Mo. 64055
Phone: 816-252-2219

KENNETH I. GRISSINGER
911 Argyle Building
306 East 12th Street

APPENDIX

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF KANSAS

CIVIL ACTION NO. 79-2252

LORRIN LEE SIXTA, Plaintiff, vs. UNITED STATES OF AMERICA, Defendant.	)	REPORTER'S TRANSCRIPT VOLUME III April 22, 1981

Proceedings before the HONORABLE SHERMAN G. FINESILVER, U. S. District Judge, sitting by designation, United States District Court for the District of Kansas, beginning at 7:15 o'clock a.m., on the 22nd day of April, 1981, in Courtroom 135, United States Courthouse, Kansas City, Kansas.

(there was a recess then taken at 9:45 o'clock a.m., after which the following further proceedings were had herein, to-wit at ten o'clock a.m.:)

THE COURT: The record should reflect that the attorneys have concluded their presentation of evidence and their arguments.

The Court at this time will deliver its bench ruling on this case.

The Court will deliver its findings of fact and conclusions of law from the bench. However, the Court reserves the right, in the event that there is a request that the record be transcribed, to edit and enlarge upon these remarks, and the Court reserves the right, after the record is transcribed, to prepare a written memorandum opinion and to make such grammatical and sentence structure changes as may be warranted.

These remarks and the bench ruling constitutes our findings of fact and conclusions of law as required under Rule 52 of the Federal Rules of Civil Procedure.

Initially the Court makes the observation, Mr. Sixta, that your attorneys could not have presented any better case on your behalf.

They have been most assiduous, most careful, most interested, most professional, and in a very aggressive way have represented

the best interests of Mr. Sixta.

In like manner, the attorneys representing the Defendant Department of Justice, even though they represent an inanimate body, they represented the Department in a professional way, a committed way and an interested way.

This case involves a proceeding brought under the Federal Tort Claims Act, to-wit the National Influenza Immunization Program of 1976, referred to as the Swine Flu Act, where Mr. Sixta seeks recovery from the United States for damages allegedly sustained as a result of his receipt of the Swine flu inoculation.

He contends that he suffered GBS, Guillain-Barre syndrome, a serious neurological disorder, as the proximate result of his inoculation.

In this case, the Government has stipulated that Mr. Sixta suffered GBS some time subsequent to his vaccination. In accordance with Paragraph 9 of the final pretrial order entered by the transferee

court, Judge Gesell, Plaintiff need only prove a causal connection between the vaccine and GBS. He is not required to prove any theory of recovery or liability in order to recover damages.

For a background of the Swine Flu Act and its genesis and proceedings thereunder, we direct counsel to the case of Alvarez vs. United States, 495 F. Supp. 1188, District of Colorado, 1980, and Bean, B-e-a-n, vs. United States, an unreported decision, 79-F-571, District of Colorado, August 19, 1980.

At trial the Plaintiff has contended that he developed symptoms which may be attributed to his GBS shortly after his vaccination.

Mr. Sixta did not testify. In contrast, the Defendant has asserted that Plaintiff's GBS had its onset in September of 1977, and that he experienced no symptoms during the ten months between his inoculation and the onset of GBS that are even remotely related to the neurological dysfunction.

The following reflect our findings and

conclusions on the sole issue before us; namely, whether or not there is a causal connection between Plaintiff's GBS and the Swine flu immunization.

On November 4th, 1976, the Plaintiff received a Swine flu vaccination in Alexandria, Minnesota. At that time he was thirty-seven years of age and employed as a pilot. The evidence revealed that prior to his inocluation he was in excellent physical condition, excellent health.

The medical records of the Plaintiff and testimony of his treating physician, Dr. Daniel Lauer, who had been Plaintiff's general internist since 1969, and Dr. Charles Weinstein, the attending neurologist, indicate that Plaintiff remained in good health until the acute onset of his GBS in September of 1977.

However, Dr. Elsworth Alvord testified that based on his review of several letters and Plaintiff's medical records a few days after Plaintiff's vaccination, he began having intermittent episodes of weakness and

numbness in his left arm, especially in the morning, and also noticed some fleeting sharp pain in his left groin region which was also an intermittent problem.

The groin pain is described in Dr. Lauer's notes of Plaintiff's office visit on April 11th, 1977, as an episode, "about three weeks ago of stabbing anterior thigh pain which has since disappeared."

Dr. Lauer testified that he considered these complaints insignificant to Plaintiff's diagnosis and to his opinion that Plaintiff's GBS began in September of 1977.

It's one of the Plaintiff's contentions that these pains marked the onset of his GBS. From the testimony of Drs. Lauer and Weinstein we find the Plaintiff's GBS did not begin until September of 1977 when he was hospitalized after an acute episode.

On the morning of September 8th, 1977, Mr. Sixta noticed some difficulty moving his bowels. That same morning at breakfast he had difficulty swallowing his food.

Later that day, he began noticing

weakness in his legs which by evening had ascended to include his arms and his hands.

On the evening of September 8th, 1977, Mr. Sixta was admitted to St. Luke's Hospital, Kansas City, Missouri. At the time of his admission to the hospital he could walk, but only with difficulty.

He was diagnosed by Dr. Weinstein as suffering from GBS. On examination, Dr. Weinstein found that Plaintiff's deep tendon reflexes were barely present in his upper and lower extremities, except that the left patella, the knee jerk, was essentially normal and active.

His lumbar puncture showed that the Plaintiff's cerebrospinal fluid protein level was at the upper limit of normal.

The Plaintiff remained hospitalized for slightly over one month. During hospitalization, Plaintiff's condition deteriorated to the point where he was unable to lift most of his muscles against gravity.

He also developed bilateral facial nerve weakness. Before his discharge, both of those

conditions had improved. At the time of his discharge, Plaintiff had begun physical therapy and could walk.

At the time of trial, Mr. Sixta suffered from weakness, fatigue and anxiety, even though perhaps clinically he has been rehabilitated. It is undetermined, however, whether the weakness and fatigue are residuals of his GBS. However, in this phase of the trial it's not necessary to make that determination.

In the trial the Court had the benefit of the following experts and their testimony: Perry Morgan, a Ph.D., Dr. Elsworth Alvord, Dr. Charles Weinstein, Dr. Neal Nathanson, Dr. Dewey Ziegler.

The focus of the medical testimony was on the date of onset of Plaintiff's GBS, and whether his GBS was causally related to the Swine flu vaccine.

Dr. Alvord, who was qualified as an expert in experimental immunology and neuropathology, testified concerning two hypotheses of Mr. Sixta's illness and its

causal connection to the Swine flu vaccine.

Dr. Alvord has not had any direct care of patients since 1950, has not examined Mr. Sixta. He is not board certified in the field of neurology.

He testified, among other things, that the longer the period between onset and vaccination, the less likely of cause-and-effect.

The cross-examination brought out that in his opinion there was a causal connection between the Swine flu and the GBS, but Dr. Alvord stated that that perhaps was based on speculation.

The first hypothesis is that Mr. Sixta's GBS began a few weeks after his Swine flu vaccination and was manifested by asymmetrical weakness.

As previously noted, we find the evidence insufficient to justify a conclusion that Plaintiff's GBS started before September of 1977.

Dr. Alvord's second hypothesis was that, even assuming that Mr. Sixta's GBS began in

September of 1977, it is reasonably probable that the vaccine caused the GBS.

The primary reason for this theory is that in experimental allergic neuritis, EAN and experimental allergic encephalomyelitis, EAE, the supposed animal model for GBS, Dr. Alvord has seen cases of EAN or EAE first clinically manifest themselves more than one year after being injected with the sensitizing agent.

However, Dr. Alvord has not published his studies or reached an explanation for the lengthy latency period between sensitization and the appearance of clinical symptoms.

In addition, Dr. Alvord has conceded that his studies were not conducted under tight controls. We find that the studies do not bear the imprimatur at this time of the medical community.

They are not to be submitted for publication. Further, the testimony reflects in our view that EAE and EAN are not exact replicas of human GBS, nor do they explain

how or why GBS occurs.

Standing alone, the replicas or the results of Dr. Alvord's studies with rabbits are insufficient to carry Plaintiff's burden of proof, notwithstanding the findings that the latency period could be close to a year.

Dr. Morgan, a Ph.D. in microbiology, testified concerning the mechanism by which the Swine flu vaccine could create an autoimmune reaction which causes GBS.

It's Dr. Morgan's opinion that the vaccine could have caused Mr. Sixta's GBS, and that Dr. Morgan did interview Mr. Sixta once further. He testified that the symptoms and the disease could be consistent with the vaccination.

We find that Dr. Morgan has had little experience with GBS and the Swine flu immunization and any correlation between those two, and his most recent experiment dealt with equine, horse, Herpes I.

Dr. Morgan had no experience with diagnosis of GBS or no experience in neurology. He also testified -- Dr. Morgan --

to-wit that Plaintiff could have been exposed to three major strains of flu viruses during his life period which in effect could include viral infection and the system could be sensitized. We have considered the testimony in that regard of Dr. Morgan.

Dr. Lauer, who was Plaintiff's treating internist from 1969 through '79, testified that Mr. Sixta first developed signs and symptoms of GBS in September of '77, and that Plaintiff never complained to him or exhibited signs or symptoms of neurological disorder between November 4th, 1976, and September of 1977.

Dr. Lauer further testified that none of the symptoms which Plaintiff testified he experienced during that period are attributable to GBS. He draws a distinction between polyneuropathies and GBS.

In his professional judgment all polyneuropathies are not GBS, and that there is a distinction; to-wit polyneuropathies can have a gradual smoldering, sleeping-type of manifestation, and in his view GBS has an

acute ascending procedure quite different in manifestation and symptomatology than other polyneuropathies.

He testified that it was not critical to a diagnosis of no causal connection between the Swine flu immunization and the GBS that the Plaintiff was not asked if he received the Swine flu shot. This was not essential to the diagnosis in September of 1977.

It was Dr. Lauer's opinion that the onset of Plaintiff's GBS was in September of 1977. It is important that Dr. Lauer testified that there was no history of weakness in the arms and legs as reported to him by the Plaintiff before September of 1977 of any noticeable degree, or any noteworthy clinical or symptomatological degree.

Dr. Weinstein, a board certified neurologist, treated Mr. Sixta during his hospitalization in September and October of 1977, and on an out-patient basis through November of '79.

He testified that Plaintiff never gave

him a history of symptoms attributable to neurological disorder prior to September of 1977. He stated that there was no acute phase earlier in the history.

He further testified that the symptoms Plaintiff testified that he had experienced between November of '76 and September 1977 are not attributable to GBS.

He heightened his testimony that there was no acute onset, there was no symmetry, that none of the characteristics that are generally set forth as being guidlines for GBS and are set forth in the Schonberger study that we will allude to and also the Schonberger replication that appears in the Annals of Neurology in the supplement has been admitted in evidence in this case.

Dr. Weinstein further testified that in his opinion Plaintiff's GBS began in September of 1977 and was not caused by the Swine flu vaccine Plaintiff received on November 4th, 1976.

The primary reason for Dr. Weinstein's

opinion that no causal relationship exists is the length of time between the vaccination and the onset of Plaintiff's acute GBS.

Dr. Weinstein found nothing in Mr. Sixta's medical history that indicated that the GBS began any earlier. He further testified that based on his review of the medical literature, particularly the study by Schonberger at the Center for Disease Control, the longest latency period is ten weeks between the antecedent event and GBS. In approximately 30 to 50 percent of the cases of GBS there is no identifiable antecedent event.

The other witnesses said this could be pretty much standardized at 50 percent. They also testified that the period in this case exceeds what is acceptable as a latency period.

He further testified that the Plaintiff gave no history of the weakness in his legs prior to September of 1977.

Dr. Weinstein discounted the Saida

study, Plaintiff's Exhibit 3 and the Lublin study, Plaintiff's Exhibit 1, concerning EAE or EAN because in his view neither are clinically identical to GBS and because of the initial stage of the Lublin studies.

The Saida study, entitled Experimental Allergic Neuritis Induced by Galactocerebroside, presented at the proceedings of a conference sponsored by the Krock Foundation concerning GBS, was attended by physicians and the papers presented were published in Supplement 9 to the Annals of Neurology in April 1981.

He commented on that article, and he stated further in that regard that Exhibit 1 and considered that the Saida study reported that eleven of the twenty-four rabbits developed neurological disorders of the peripheral nervous system from two months to one year after being immunized with the GC substance.

Drs. Weinstein and Ziegler testified that EAN in their view is not an exact replica of GBS in humans.

Further, from the totality of the evidence we conclude that Plaintiff's GBS began in September 1977, ten months after the Swine flu vaccination.

We do not find that the symptoms Plaintiff experienced during the ten-month interval in any way related to his GBS, nor do we find that they marked the onset of his GBS.

We find that GBS is generally classified as a motor neuropathy with motor weakness of more than one limb. This is set forth in Alvarez vs. United States and also the CDC study.

The symptoms usually appear acute and progress rapidly. That GBS is characterized by progressive motor weakness of more than one limb is supported by Asbury's paper entitled Diagnostic Consideration in Guillain-Barre Syndrome, also presented at the Krock Conference.

This simply was not the course of Plaintiff's condition as related by Dr. Alvord. While we recognize there are

variants of GBS, we do not believe that Plaintiff's thigh pain in March or April of 1977, or his groin pain shortly after his inoculation are signs or symptoms of GBS.

Having determined that the Plaintiff's GBS started in September of 1977, now we come to the question whether it was caused by the Swine flu immunization.

The Minnesota law governs the issue of probable cause because that's where the Plaintiff was inoculated, 28 U.S.C. Section 1346(b), Richards vs. United States, 369 U.S. 1.

Under Minnesota law, in cases such as this where the issue of causation is not within the common knowledge of laymen, Plaintiff has the burden of proving by expert testimony by Defendant's acts or omissions. Walton vs. Jones, 286 N.W.2d 710.

Proof of causation cannot rest on conjecture and the mere possibility of causation is not enough to sustain Plaintiff's burden of proof. Walstad vs. University of Minnesota Hospitals, 442 F.2d

Additionally, medical testimony which does nothing more than show a mere possibility, suspicion or conjecture that a causal connection exists, without any foundation for the exclusion of other admittedly possible causes does not sustain Plaintiff's burden of proof.

Likewise, an opinion without careful scientific investigation and examination will be insufficient. Bernloehr vs. Central Livestock Order Buying Company, 208 N.W.2d 753, a Minnesota case.

In the instant case, we have received the opinions of several doctors as to the causal connection between Plaintiff's GBS and the Swine flu vaccine.

As previously noted, Dr. Weinstein, Plaintiff's treating neurologist, found that was no causal connection between Plaintiff's inoculation and his GBS.

Also Dr. Nathanson, who is the chairman of the Department of Microbiology at the University of Pennsylvania Medical School,

testified that based on his review of Plaintiff's medical records and his background, the Plaintiff's GBS was not caused by the Swine flu vaccination he received on November 4th, 1976.

Dr. Nathanson was a professor of medicine and head of the Division of Infectious Diseases at the Department of Epidemiology at John Hopkins. He was formerly the editor-in-chief of the Journal of Epidemiology for many years, terminating in July of 1979.

We find him to be experienced in the fields of epidemiology and virology. He has testified unequivocally that the Schonberger study is valid and on which he can base a relationship on the Swine flu and its effect on GBS.

Also the Michigan study, which was not to any degree influenced by the CDC study which relates a longer period of surveillance and study, supports the findings of the Schonberger study, to-wit the onset is four or five weeks that levels

off right around ten weeks, and thereafter there is little if any difference in the population and the vaccinated group and nonvaccinated group in regard to incidents of GBS.

So two independent studies with a large sample have come to the same conclusion that after ten weeks, with a sprinkling into the twelfth week, as being outside latency period between the antecedent or inciting event and the initiation or the manifestation of the GBS.

While we are not bound by any ten- or twelve-week period, it appears at this juncture, anyway, that in light of reason and medical testimony, that that is the acceptable scientific evaluation.

No doubt at some future time there will be a meandering period beyond that period. However, at this time any period thereafter must be done on an individual basis, and we, by stretching and straining, cannot find that to be the case here over the period from November to the onset in September.

Dr. Ziegler, a board certified neurologist, who is chairman of the Department of Neurology at the University of Kansas Medical Center, testified that in his opinion, Plaintiff's GBS was not caused by the Swine flu vaccine.

The primary reason for his opinion is that in Dr. Ziegler's view ten months is too long a period for a causal relationship to appear between the vaccine and the onset of GBS.

He also testified that each year many people have the onset of GBS without any regard to vaccinations. That each year prior to the vaccination people had GBS. They will continue to have GBS notwithstanding their long period of substantial duration after the 1976 inoculation.

Dr. Ziegler stated that Mr. Sixta did not develop GBS prior to September 1977 because the medical records do not demonstrate that he experienced the core symptom of that disorder, symmetrical weakness.

In Dr. Ziegler's view there is no evidence that an event occurring more than twelve weeks beyond the GBS is a causative factor in the disease.

He further testified that the EAE and EAN models are not significant in determining maximum latency period between an event and the onset of GBS.

He further stated that there have been no break-throughs which analogize EAN to GBS, and that results found in EAE cannot be applied to EAN or GBS because the latter involve the peripheral nervous system whereas the former involves the central nervous system. There is a difference between the two.

Dr. Alvord says they can be used interchangeably. There is a conflict of testimony in that regard. We are satisfied the better screened view indicates there is a separation between EAE and EAN, and only EAN touches upon the peripheral nervous system which, of course, is the hallmark of

GBS.

The evidence established that the exact organic cause of GBS has not been scientifically proven. In such cases, the causal connection between the disease process and a preceding event can only be established based on reported clinical observations and epidemiologic studies.

Our review of the medical literature reveals only one study that suggests a causal connection between GBS and an event ten weeks earlier.

In that study conducted by Schonberger, et al., from the American Journal of Epidemiology, entitled "Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program of 1976," the authors concluded that there was an etiologic relationship between the Swine flu vaccine and GBS, but that such relationship extended for ten weeks at most.

In the Schonberger study, the increased incidence of GBS occurred primarily within the first five weeks following vaccination.

Prior studies had indicated that events that occurred within four weeks of the onset of a neurologic symptom could be considered as a possible cause of GBS. This is the forty-two year study from the Mayo Clinic entitled "Guillain-Barre Syndrome, a 42 Year Epidemiologic and Clinical Study." We also consider Chapter 56, an article by Dr. Barry Arnason in Peripheral Neuropathy, a two volume work by Dyck, Saunders Press.

Guillain-Barre beginning ten months after an event is far beyond any interval in which GBS has been associated with an event.

We would care to comment on the article by Arnason because that has been called to the Court's attention by Plaintiff's counsel in this case, and that article that has been called to the Court's attention touching on Chapter 56, has suggested to the Court that there can be a relapsing type of polyneuropathy, but we comment that that view of Dr. Arnason relates to individuals who had GBS, recovered and then had another

incidence of GBS, two discernible incidents of GBS, and we find that not to be the case here.

And while we have considered that approach, we are satisfied that Dr. Arnason's testimony in this case, anyway, indicates by excerpt that the period is well within the ten-week period, probably four to six weeks.

We comment further that Plaintiff presented evidence concerning experimental studies done with animals which purport to represent models of GBS and MS in humans. And from this primarily is much of the heart of Plaintiff's case.

Those studies, Plaintiff's Exhibits 3 and 1, report that mice or rabbits may develop initial signs of neurological disease up to one year after being injected with large doses of ground animal nerve tissue.

We find these studies to be unpersuasive on the maximum interval in which the Swine flu vaccine could cause GBS in humans.

First, the substances injected into the animals were not contained in the Swine flu vaccine.

Secondly, they were injected with fairly large doses of the nerve. And, thirdly, the EAE model pertains to the central nervous system of animals, and it is not analogous to GBS in humans which is a disorder of the peripheral nervous system.

EAN is not recognized as an exact replica of the model in humans. EAE and EAN are not established as GBS. However, we have considered EAE and EAN and their importance in this case, and we can only observe that there is a suggestion or possibility that there may be susceptibility to GBS of a genetic determination, but that the research in this field is in its formative stage, and in our view too recent to be evaluated critically, and it has not been established that EAE and EAN studies are persuasive in GBS studies.

For those reasons we are not persuaded that the length and latency period between

injection and onset of neuropathy in EAE or EAN demonstrates that the Swine flu vaccine could cause GBS in humans nine or ten months after inoculation.

We also considered and reject that Plaintiff's genetic system and immune system to the degree here that for some manifestation of the Swine flu immunization that the system that matched with his unique genetic system caused the GBS.

It is hypothetical. It has not been established to the Court's satisfaction in this case.

From the totality of the evidence, including the medical literature, the expert testimony presented at trial, the Court finds and concludes that it is not probable that Plaintiff's GBS was caused by the Swine flu vaccine he received on November 4th, 1976.

The testimony of Dr. Alvord and Dr. Morgan that such a causal connection exists is conjectural and not supported by the present state of medical knowledge, and

under Minnesota law it does not carry the burden of proof.

Drs. Lauer, Ziegler and Weinstein are in accordance with established medical and scientific principles and the state of scientific art at this time.

Further, the epidemiological studies indicate the maximum interval between vaccination and onset of GBS is ten weeks for a causal connection to exist.

While these studies do not bind the Court, we find they are widely accepted in the community, particularly the CDC study, and are highly persuasive evidence that the Swine flu vaccine did not cause Mr. Sixta's GBS.

At trial Plaintiff contended that he might have contracted recurrent polyneuropathy as a result of the Swine flu vaccine. Drs. Weinstein and Ziegler, however, testified that recurrent or chronic polyneuropathy is a different clinical entity than acute GBS.

This view is also supported by Asbury in

the paper presented to the Krock Foundation and in literature.

In their view GBS in its traditional form, as we view it in this context and this case, as provided for under the Act, is different than other neuropathies and all neuropathies are not brought under the sweep of GBS.

It is not a catch-all for all types of neuropathies, be they central or peripheral.

We sympathize with the hardships that Mr. Sixta has endured as a result of his GBS, but the fact remains that the Government is only liable where a Plaintiff proves that his GBS was caused by the vaccine.

Every case with GBS is not attributable to the vaccine. This is a case in our view in which there is no causal connection. In this case the evidence leads us to the inescapable conclusion that something other than the Swine flu vaccine caused Mr. Sixta's GBS.

For these reasons we find in favor of the Government and against the Plaintiff. Appropriate judgment shall be entered in this case. Each side to pay its or their own costs.

We simply find that the Plaintiff has failed to carry its burden of proof in this case. The Defendant, to the contrary, has established, not by a preponderance of the evidence, but by substantial and clear and convincing evidence, that there is no causal connection between the GBS and Mr. Sixta and the Swine flu immunization.

In conclusion we hold that Plaintiff has failed to prove by a preponderance of the evidence that the vaccine was a substantial factor in his GBS.

We expressly find that Plaintiff did not contract GBS or any other neuropathy as a result of the Swine flu vaccination.

(Opinion Filed: December 7, 1984)

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

LORRIN LEE SIXTA, Plaintiff-Appellant,	)	
v.	)	No. 81-1612 (D.C. No. 79-2252) (D. Kan.)
UNITED STATES OF AMERICA, Defendant-Appellee.	)	

ORDER AND JUDGMENT

Before BARRETT, McKAY and LOGAN, Circuit Judges

This three-judge panel has determined unanimously that oral argument would not be of material assistance in the determination of this appeal. See Fed. R. App. P. 34(a); 10th Cir. R. 10(e). The cause is therefore ordered submitted without oral argument.

This is an appeal from the judgment of the United States District Court for the District of Kansas (Judge Sherman G.

Finesilver) dismissing plaintiff's action against the United States for personal injury allegedly caused by the swine flu vaccination administered during the National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 42 U.S.C. Sec.247(j)-(l) (Swine Flu Act.)

Plaintiff filed this action on September 11, 1979, seeking damages against the United States under the Swine Flu Act. Trial was to the court on April 22, 1981. The court entered a bench ruling constituting findings of fact and conclusions of law in favor of the United States and dismissing the action on the merits. On May 7, 1981, plaintiff moved to alter judgment, and when that motion was denied, plaintiff filed a notice of appeal.

At trial the only issue was that of causation, defendant having stipulated that plaintiff received a swine flu shot in Alexandria, Minnesota, on November 4, 1976,

and that plaintiff contracted Guillain-Barre Syndrome (hereafter "GBS") some ten months later. Under the Federal Tort Claims Act as incorporated into the Swine Flu Act, the applicable law regarding causation was that of Minnesota. 42 U.S.C. Sec.247b(k) (2) (A); 28 U.S.C. 1346(b), 2674; Richards v. United States, 369 U.S. 1 (1962).

On appeal, plaintiff presents four issues: (1) whether the court wrongfully directed invasion of purported work product trial preparation materials; (2) whether the trier of fact erred in "considering matters dehors the record"; (3) whether the court properly applied and interpreted Minnesota law of proximate causation; and (4) whether the district court had prejudged the merits of the case in advance of reception of the total evidence and arguments of counsel.

The methods of discovery are governed in general by Fed. R. Civ. P. 26. Rule 26 (b) (4) governs the scope of discovery concerning

experts. Subdivision (b) (4) separates these experts into four categories, only two of which are relevant here: (1) experts a party expects to use at trial; and (2) experts retained or specially employed in anticipation of litigation or preparation for trial but not expected to be used at trial. Different limitations apply to the extent of discovery with regard to these two types of experts. If the expert is to be called at trial, the opponent may learn by interrogatories the names of these trial witnesses and the substance of their testimony, but further discovery concerning them can be had only on motion and court order. Ager v. Jane C. Stormont Hospital & Training, 622 F.2d 496, 500 (10th Cir. 1980).

A decision on discovery orders is within the sound discretion of the trial court. Ryan v. Hatfield, 578 F.2d 275, 276 (10th Cir. 1978); Silkwood v. Kerr-McGee Corp., 563 F.2d 433, 436 (10th Cir. 1977). In order for there to be a finding of abuse of discretion, the

district court must have acted improvidently, and there must be a showing of actual harm to substantial rights of plaintiff. Belcher v. Bassett Furniture Co. Industries, Inc., 588 F.2d 904 (4th Cir. 1978). Plaintiff's claim that defendant avoided the immunology approach is an overbroad assertion lacking in a specific connection to the discovered material. Defendant could have taken the same strategic approach to the case simply because defendant knew that plaintiff was planning to call an immunologist to testify.

An examination of the deposition transcript regarding the discovery of these documents does not provide any insight as to why plaintiff claims they are protected by the work product doctrine. It appears that, other than the file cards, the documents were prepared by Dr. Morgan and contained information as to his opinions, not that of the attorneys. The file cards were prepared by counsel but they merely consist of a

listing of the medical authorities consulted by both Dr. Morgan and plaintiff's counsel. None of these documents, or any other information discovered by defendant, appear from this record to consist of "mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party" within the meaning of Fed. R. Civ. P. 26(b) (3). Plaintiff has not met his burden of showing that the information discovered is of the type protected by the work product doctrine. See United States v. Bump, 605 F.2d 548, 551 (10th Cir. 1979). It would be helpful to the resolution of this issue to know the nature of the documents which were discovered over plaintiff's objection. Plaintiff has failed, however, to include these documents as part of the record on appeal. It is plaintiff's responsibility to include these items in the record, and failure to do so stifles adequate review of this issue on appeal. Id.

Moreover, the record reveals that the district court, in deciding the issue of whether these documents were discoverable, determined that plaintiff had stipulated to their discovery. Plaintiff now asserts that he had not waived his objection but had only agreed to discovery in order to prevent his witness from being held in contempt. Again, a transcript of the hearing on the discovery of these documents was not made a part of the record. Plaintiff has failed to make the requisite showing that (1) the items discovered were in fact work product; and (2) if they were work product, that the district court abused its discretion in allowing their discovery to the prejudice of plaintiff's case.

Plaintiff's claim concerning the Mayo Clinic article stems from a misreading of the record. In its bench ruling, the court discussed the Schoenberger study, admitted into evidence as defendant's Exhibit Q. The

court's reference to the "Mayo Clinic study" is merely an explanation of the "prior studies" which are discussed in the body of the Schoenberger study. Plaintiff's other claims regarding consideration of matters outside the record are similarly without merit.

Plaintiff's further argument that the district court prejudged the case prior to final submission is simply without foundation. An examination of the district court's final order dismissing plaintiff's action indicates that the findings and conclusions are supported by the record. There is no evidence of predetermination on the part of the trial court.

Plaintiff's final claim that the district court misapplied Minnesota's substantial factor test is based on the erroneous position that because plaintiff's two experts testified that, in their opinion, the swine flu vaccination was a substantial

factor in causing plaintiff's GBS, the district court had no choice but to conclude that causation had been proven. Plaintiff was obliged to show by a preponderance of the evidence that the swine flu vaccination proximately caused his GBS. See Silver v. Redleaf, 194 N.W.2d 271, 273 (Minn. 1972). Proof of causal connection must be more than "merely consistent with the plaintiff's theory of the case." Bernloehr v. Central Livestock Order Buying Co., 208 N.W.2d 753, 754 (Minn. 1973); Walton v. Jones, 286 N.W.2d 710, 715 (Minn. 1979). There must be evidence "which affords a reasonable basis for one to conclude that it is more likely than not that defendant's conduct was a substantial factor in bringing about the result." Walstad v. University of Minnesota Hospitals, 422 F.2d 634, 639 (8th Cir. 1971). The expert testimony must be based on "an adequate factual foundation that the thing alleged to have caused the result not only might have

caused it but in fact cause it."
Bernloehr, 208 N.W.2d at 755.

Defendant produced expert witnesses who stated that, in their opinion, the swine flu vaccine was unrelated to plaintiff's GBS. In the face of this conflict in the evidence, the district court may exercise its judgment in deciding the credibility of the witnesses and testimony presented. Gundy v. United States, 728 F.2d 484, 489 (10th Cir. 1984). This includes an evaluation of which experts present the more reasonable and authoritative position based on the evidence as a whole. Id. Therefore, the district court applied the substantial factor test correctly in deciding that plaintiff had not proven by a preponderance of the evidence that the vaccine was a substantial factor in causing plaintiff's GBS. See 10th Cir. R. 17(b).

The judgment of the United States District Court for the District of Kansas is AFFIRMED.

HOWARD K. PHILLIPS, Clerk

(Filed: February 7, 1985)

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

JANUARY TERM - February 4, 1985

LORRIN LEE SIXTA, Plaintiff-Appellant,	)	
v.	)	No. 81-1612
UNITED STATES OF AMERICA, Defendant-Appellee.	)	

This matter comes on for consideration of plaintiff's petition for rehearing, with suggestion for rehearing en banc, which we also construe as a motion to recall the mandate. We hereby recall the mandate.

Upon consideration of the merits of the petition for rehearing, the petition is denied by the panel to whom the case was submitted.

The petition for rehearing having been denied by the panel to whom the case was submitted, and no member of the panel nor judge in regular active service on the court having requested that the court be polled on

rehearing en banc, Fed. R. App. P. 35, the suggestion for rehearing en banc is denied.

The mandate shall issue forthwith.

HOWARD K. PHILLIPS, Clerk

PUBLIC LAW 94-380- AUG. 12, 1976

AN ACT

To amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program.

It is enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "National Swine Flu Immunization Program of 1976". Sec. 2. Section 317 of the Public Health Service Act (42 U.S.C.201) is amended by inserting after subsection (i) the following new subsections:

"(j) (1) The Secretary is authorized to establish, conduct, and support (by grant or contract) needed activities to carry out a national swine flu immunization program

until August 1, 1977 (hereinafter in this section referred to as the 'swine flu program'). The swine flu program shall be limited to the following:

"(A) The development of a safe and effective swine flu vaccine.

"(B) The preparation and procurement of such vaccine in sufficient quantities for the immunization of the population of the States.

"(C) The making of grants to State health authorities to assist in meeting their costs in conducting or supporting, or both, programs to administer such vaccine to their populations, and the furnishing to State health authorities of sufficient quantities of such swine flu vaccine for such programs.

"(D) The furnishing to Federal health authorities of appropriate quantities of such vaccine.

"(E) The conduct and support of training of personnel for immunization activities described in subparagraphs (C) and (D) of

this paragraph and the conduct and support of research on the nature, cause, and effect of the influenza against which the swine flu vaccine is designated to immunize, the nature and effect of such vaccine, immunization against and treatment of such influenza, and the cost and effectiveness of immunization programs against such influenza.

"(F) The development, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and implementation of a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each individual to whom such vaccine is to be administered. Such consultation shall be completed within two weeks after enactment of this Act, or by September 1, 1976, whichever is sooner. Such procedures shall include the information

to their rights and remedies arising out of the administration of such vaccine.

"(G) Such other activities as are necessary to implement the swine flu program.

"(2) The Secretary shall submit quarterly reports to the Congress on the administration of the swine flu program. Each such report shall provide information on-

"(A) the current supply of the swine flu vaccine to be used in the program;

"(B) the number of persons inoculated with such vaccine since the last report was made under this paragraph and the immune status of the population;

"(C) the amount of funds expended for the swine flu program by the United States, each State, and any other entity participating in the program and the costs of each such participant which are associated with the program, during the period with respect to which report is made; and

"(D) the epidemiology of influenza in the United States during such period.

"(3) Any contract for procurement by the United States of swine flu vaccine from a manufacturer of such vaccine shall (notwithstanding any other provision of law) be subject to renegotiation to eliminate any profit realized from such procurement (except that with respect to vaccine against the strain of influenza virus known as influenza A/Victoria/75 profit shall be allowed but limited to an amount not exceeding a reasonable profit), as determined pursuant to criteria prescribed by the Secretary, and the contract shall expressly so provide. Such criteria shall specify that any insurance premium amount which is included in the price of such procurement contract and which is refunded to the manufacturer under any retrospective, experience-rating plan or similar rating plan shall in turn be refunded to the United States.

"(4) No funds are authorized to be appropriated to carry out the activities of

the swine flu program authorized in subparagraphs (A), (B), (D), (E), and (F) of paragraph (1) of this subsection in addition to the funds appropriated by Public Law 94-266.

"(k) (1) (A) The Congress finds that -

"(i) in order to achieve the participation in the program of the agencies, organizations, and individuals who will manufacture, distribute, and administer the swine flu vaccine purchased and used in the swine flu program and to assure the availability of such vaccine in interstate commerce, it is necessary to protect such agencies, organizations, and individuals against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of such vaccine;

"(ii) to provide such protection and to establish an orderly procedure for

the prompt and equitable handling of claims by persons alleging such injury or death, it is necessary that an exclusive remedy for such claimants be provided against the United States because of its unique role in the initiation, planning, and administration of the swine flu program; and

"(iii) in order to be prepared to meet the potential emergency of a swine flu epidemic, it is necessary that a procedure be instituted for the handling of claims by persons alleging such injury or death until Congress develops a permanent approach for handling claims arising under programs of the Public Health Service Act.

"(B) To -

"(i) assure an orderly procedure for the prompt and equitable handling of any claim for personal injury or death arising out of the administration of such vaccine; and

"(ii) achieve the participation in the swine flu program of

(I) the manufacturers and distributors of the swine flu vaccine,

(II) public and private agencies or organizations that provide inoculations without charge for such vaccine or its administration and in compliance with the informed consent form and procedures requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and (III) medical and other health personnel who provide or assist in providing inoculations without charge for such vaccine or its administration and in compliance with such informed consent form and

procedures requirements;

it is the purpose of this subsection to establish a procedure under which all such claims will be asserted directly against the United States under section 1346(b) of title 28, United States Code, and chapter 171 of such title (relating to tort claims procedure) except as otherwise specifically provided in this subsection.

"(2) (A) The United States shall be liable with respect to claims submitted after September 30, 1976 for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it under such section 1346(b) and chapter 171, except that -

"(i) the liability of the United States arising out of the act or omission of a program participant may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty;

"(ii) the exceptions specified in section 2680(a) of title 28, United States Code, shall not apply in an action based upon the act or omission of a program participant; and

"(iii) notwithstanding section 2401(b) of title 28, United States Code, if a civil action or proceeding for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program is brought within two years of the date of the administration of such vaccine and is dismissed because the plaintiff in

such action or proceeding did not file an administrative claim with respect to such injury or death as required by such chapter 171, the plaintiff in such action or proceeding shall have 30 days from the date of such dismissal or two years from the date the claim arose, whichever is later, in which to file such administrative claim.

"(B) For purposes of this subsection, the term 'program participant' as to any particular claim means the manufacturer or distributor of the swine flu vaccine used in an inoculation under the swine flu program, the public or private agency or organization that provided an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with the informed consent form and procedures requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and the medical and other health personnel who provided or assisted in

providing an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with such informed consent form and procedures requirements.

"(3) The remedy against the United States prescribed by paragraph (2) of this subsection for personal injury or death arising out of the administration of the swine flu vaccine, under the swine flu program shall be exclusive of any other civil action or proceeding for such personal injury or death against any employee of the Government (as defined in section 2671 of title 28, United States Code) or program participant whose act or omission gave raise to the claim.

"(4) The Attorney General shall defend any civil action or proceeding brought in any court against any employee of the Government (as defined in such section 2671) or program participant (or any liability insurer thereof) based upon a claim alleging personal injury or death arising out of the

administration of vaccine under the swine flu program. Any such person against whom such civil action or proceeding is brought shall deliver all process served upon him (or an attested true copy thereof) to whoever is designated by the Secretary to receive such papers, and such person shall promptly furnish copies of the pleadings and process therein to the United States attorney for the district embracing the place wherein the civil action or proceeding is brought, to the Attorney General, and to the Secretary.

"(5) (A) Upon certification by the Attorney General that a civil action or proceeding brought in any court against any employee of the Government (as defined in such section 2671) or program participant is based upon a claim alleging personal injury or death arising out of the administration of vaccine under the swine flu program, such action or proceeding shall be deemed an action against the United States under the

provisions of title 28, United States Code, and all references thereto. If such action or proceeding is brought in a district court of the United States, then upon such certification the United States shall be substituted as the party defendant.

"(B) Upon a certification by the Attorney General under subparagraph (A) of this paragraph with respect to a civil action or proceeding commenced in a State court, such action or proceeding shall be removed, without bond at any time before trial, by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and be deemed an action brought against the United States under the provisions of title 28, United States Code, and all references thereto; and the United States shall be substituted as the party defendant. The certification of the Attorney General with respect to program participant status shall conclusively establish such status for purposes of such

initial removal. Should a district court of the United States determine on a hearing on a motion to remand held before a trial on the merits that an action or proceeding is not one to which this subsection applies, the case shall be remanded to the State court.

"(C) Where an action or proceeding under this subsection is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided by any other law, the action or proceeding shall be dismissed, but in that event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this subsection.

"(6) A program participant shall cooperate with the United States in the processing or defense of a claim or suit under such section 1346(b) and chapter 171

based upon alleged acts or omissions of the program participant. Upon the motion of the United States or any other party, the status as a program participant shall be revoked by the district court of the United States upon finding that the program participant has failed to so cooperate, and the court shall substitute such former participant as the party defendant in place of the United States and, upon motion, remand any such suit to the court in which it was instituted.

"(7) Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative settlement or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as any costs of litigation, resulting from the failure of any program participant to carry out any obligation or responsibility assumed by it under a contract with the United

States in connection with the program or from any negligent conduct on the part of any program participant in carrying out any obligation or responsibility in connection with the swine flu program. The United States may maintain such action against such program participant in the district court of the United States in which such program participant resides or has its principal place of business.

"(8) Within one year of the date of the enactment of the National Swine Flu Immunization Program of 1976, and semiannually thereafter the Secretary shall submit to the Congress a report on the conduct of settlement and litigation activities under this subsection, specifying the number, value, nature, and status of all claims made thereunder, including the status of claims for recovery made under paragraph (7) of this subsection and a detailed statement of the reasons for not seeking such recovery.

"(l) For the purposes of subsections (j) and (k) of this section -

"(1) the phrase 'arising out of the administration' with reference to a claim for personal injury or death under the swine flu program includes a claim with respect to the manufacture or distribution of such vaccine in connection with the provisions of an inoculation using such vaccine under the swine flu program;

"(2) the term 'State' includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands; and

"(3) the term 'swine flu vaccine' means the vaccine against the strain of influenza virus known as influenza A/New Jersey/76 (Hsw 1N1), or a combination of such vaccine and the vaccine against the strain of influenza known as influenza A/Victoria/75".

SEC. 3. The Secretary of Health, Education, and Welfare shall conduct, or provide for the conduct of, a study of the scope and extent of liability for personal injuries or death arising out of immunization programs and of alternative approaches to providing protection against such liability (including a compensation system) for such injuries. Within one year of the date of the enactment of this Act, the Secretary shall report to the Congress the findings of such study and such recommendations for legislation (including proposed drafts to carry out such recommendations) as the Secretary deems appropriate.

APPROVED AUGUST 12, 1976.